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510(k) Summary

superDimension, Ltd.
Special 510(k)
superDimension inReach System
Addition of Software Functionality

Date Prepared:

07/31/2009

510(k) Applicant:

superDimension, Ltd.
8 Hamenofim St., P.O. Box 2045
Herzliya 46120
Israel
Ph: +972-(0)9-971-3700
Fax: +972-(0)9-971-3701

510(k) Application Correspondent:

Jonathan Kovach
Vice President, Quality and Regulatory Affairs
superDimension, Inc.
161 Cheshire Lane, Suite 100
Minneapolis, MN 55441
Phone: 763-210-4015
Cell : 763-360-4984
Fax : 763-210-4098
Email : jkovach@superdimension.com

Name of Device :

Trade Name :	superDimension inReach™ System
Common Name:	Bronchoscope
Classification Name:	Computed tomography x-ray system 21 CFR Part 892.1750 Product code JAK

Equivalent Legally-Marketed Device:

superDimension inReach System, K081379

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Description:

The superDimension inReach System is a device that guides a bronchoscope and endoscopic tools to a target in or adjacent to the bronchial tree on a path identified by CT scan. The superDimension inReach System also allows visualization of the target and the interior of the bronchial tree; placement of catheters in the bronchial tree; and placement of radiosurgical and dye markers into soft lung tissue to guide radiosurgery and thoracic surgery.

Intended Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Summary of Characteristics Compared to Predicate Device:

Changes are being made to the software through implementation of algorithms for CT-to-Body Automatic Initial Registration (autoIR) and dynamic registration (DR) for electromagnetic navigation bronchoscopy. These new algorithms provide alternative methods for registration and navigation. Additional views are being added including a real-time Locatable Guide (LG) tip location indicator on the 3D Map, a local view showing the CT volume cut through the LG tip location, a real-time virtual bronchoscopy view synchronized with the LG position, and a Maximum Intensive Projection (MIP) view synchronized with the LG position. The software will also provide guidance on a continuous pathway (line-based guidance) when navigating inside the 3D Map.

Minor changes are being made to the Personal and Laptop Computer. No changes are being made to the disposable products. The Instructions for Use are being changed to address the changes to the software.

Performance Data:

The changes to the algorithms and Instructions for Use were subjected to the superDimension design control process. Risk Management was performed to analyze the potential hazards associated with the changes. Appropriate design verification and validations were performed to assure the superDimension inReach System continues to be safe and effective for its intended use.

Clinical Data:
Clinical tests were not required to validate the changes to the superDimension inReach System.

Conclusion:
The superDimension inReach System is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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superDimension, Ltd. HealthCare Corporation
% Mr. Jonathan Kovach
Vice President, Quality and Regulatory Affairs
superDimension, Incorporated
161 Cheshire lane, Suite 100
MINNEAPOLIS MN 55441

Re: K092365
Trade/Device Name: superDimension® inReach™ System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: July 31, 2009
Received: August 5, 2009

Dear Mr. Kovach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092365

Device Name: superDimension® inReach™ System

Indications for Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool.

Not for pediatric use.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092365